DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Drug Notification

Form Approved: OMB No. 0910-0808
Expiration Date: January 31, 2022
See PRA Statement on page 2.

Refer to instruction sheet (Form FDA 3911 Supplement) for more information.

1. Type of Report *(Select one)*: ☒ Initial Notification ☐ Follow-Up Notification ☐ Request for Termination

2. Incident Number *(Provide this number, assigned by FDA, if you selected Follow-up Notification or Request for Termination above; see instructions.)*

3. Date of Initial Notification to FDA *(mm/dd/yyyy)*	4. Date Company Determined Product Was Illegitimate *(mm/dd/yyyy)*	5. Classification of Notification *(Select from list)*
03/25/2021		Fraudulent Transaction

Description of Product

6. Name of Product as It Appears on Label
Biktarvy 30CT

7. Primary Ingredients(s) *(if known)*
BICTEGRAVIR, EMTRICITABIN, TENOFOVIR ALAFENEMIDE FUMARATE

8. Drug Use *(Select from list)*	9. Drug Description *(Select from list)*
Human Use	Finished Prescription Drug

10. Strength of Drug	11. Dosage Form *(Select from list)*
50MG/200MG/25MG	Tablet

12. Quantity of Drug *(Number and Unit)*	13. NDC Number *(if applicable)*	14. Serial Number *(if applicable)*
3 bottles	61958-2501-01	

15. Lot Number(s)
CCXKVA, CCZCFA, CDFYCA

16. Expiration Date(s)

17. For Notification: Description of Event/Issue
See additional page

Add Page for Item 17

18. For Request for Termination of Notification: Description of why notification is no longer necessary

Add Page for Item 18

19. If you have submitted information to FDA through an alternative mechanism, check all that apply.

☐ BPDR ☐ MedWatch 3500 ☐ None
☐ FAR ☐ MedWatch 3500A ☐ Other *(Specify)*: _____

GOVERNMENT EXHIBIT
634A
1:24-cr-20255-WPD

Company/Facility Information

20. Company Name & Address

Name	Safe Chain Solutions
Address 1 *(Street address, P.O. box, etc.)*	822 Chesapeake Drive
Address 2 *(Apartment, suite, unit, building, floor, etc.)*	
City	Cambridge
State/Province/Region	MD
Country	United States
ZIP or Postal Code	21613

21. Company Category *(Select from list)*

Wholesale Distributor

22. Unique Facility Identifier *(of company named in #20)*

025667294

23. Contact Information *(Note: For the telephone, you may enter the number of either the contact person or of the company named in #20.)*

Name	Charles Boyd
Telephone Number *(Include area code)*	855-437-5727
Email Address	Charlesb@safechain.com

SUBMIT BY EMAIL

A willfully false statement is a criminal offense, pursuant to U.S. Code, title 18, section 1001.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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PRAStaff@fda.hhs.gov

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CONTINUATION PAGE FOR ITEM 17 – For Notification: Description of event/issue

In the space below, please continue the description of the event/issue.

Safe Chain received three complaints from pharmacies regarding Biktarvy. In one of the cases, the bottle was identified by the dispensing pharmacist to contain another Gilead product Stribild. Right away Gilead QC Department asked us if we purchase Stribild. We were informed from our supplier GenTek via email to "Please go ahead and destroy the product. That's a mixed batch error on our AD". We asked that specific question of Gilead. After promptly filing a complaint with Gilead's QC Dept and providing photos, we sent the product to Gilead. Safe Chain heard nothing back until yesterday.

In one of the cases, we asked Gilead if they had made a DSCSA "determination" and they indicated they have not reported to the FDA because they have merely commented but not made a DSCSA "determination." Gilead has also refused to let us know if there have been any other reports with other wholesalers.

For each complaint, Safe Chain declined these specific lots from any vendors, quarantined the specific lot, and contacted the manufacturer and immediately filing a product quality complaint with the QC Complaints Dept of the manufacturer, Gilead Sciences, Inc. (Lot CCZCFA- Gilead complaint # PR# 213279) (Lot CDFYCA- Reported to Gilead- Complaint # PR196084) (Lot CCXKVA)- Reported to Gilead- Not assigned a complaint number by Gilead's QC Dept but we have the paper trail). Where product was returned to Safe Chain, we quarantined the product, until Gilead was able to coordinate the return to their facility. We provided photos at their request. Gilead was also provided with copies of the T3 data and Safe Chain awaited "DSCSA determinations" from Gilead which were never forthcoming. Safe Chain also asked Gilead to report this to FDA if they made a determination the product was illegitimate. On March 24, 2021 our counsel at Frier Levitt, LLC received a letter from Gilead's counsel (not their QC Department) indicating what we believe to be a "determination" regarding these 3 product complaints that Safe Chain reported to Gilead. Gilead has stated that that the T3 data was false inasmuch as Gilead never sold the lots in question to their Authorized Distributer Drogueria Betances (Betances). The T3 we received from our supplier indicates this authorized distributor sold the product to GenTek who in turn sold the product to Safe Chain. That is, GenTek has indicated they purchased from Betances and this is reflected in the T3. Since the "determination" does not indicate that Gilead has or intends to report suspect product determination to the FDA, Safe Chain is doing so. Please advise us what the next steps are.

Safe Chain Solutions LLC
Cambridge, MD 21613-9408
FEI: 3009729473
04/11/15 - 05/10/21 MDD, CMP
Exhibit CMP-19 <<Page 3 of 3>>

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Drug Notification

Form Approved: OMB No. 0910-0806
Expiration Date: January 31, 2022
See PRA Statement on page 2.

Refer to instruction sheet (Form FDA 3911 Supplement) for more information.

1. Type of Report *(Select one)*: ☒ Initial Notification ☐ Follow-Up Notification ☐ Request for Termination

2. Incident Number *(Provide this number, assigned by FDA, if you selected Follow-up Notification or Request for Termination above; see instructions.)*

3. Date of Initial Notification to FDA *(mm/dd/yyyy)*	4. Date Company Determined Product Was Illegitimate *(mm/dd/yyyy)*	5. Classification of Notification *(Select from list)*
03/27/2021		Unfit for Distribution

Description of Product

6. Name of Product as It Appears on Label
BIKTARVY 30CT

7. Primary Ingredients(s) *(if known)*
BICTEGRAVIR, EMTRICITABIN, TENOFOVIR ALAFENEMIDE FUMARATE

8. Drug Use *(Select from list)*	9. Drug Description *(Select from list)*
Human Use	Finished Prescription Drug

10. Strength of Drug	11. Dosage Form *(Select from list)*
50MG/200MG/25MG	Tablet

12. Quantity of Drug *(Number and Unit)*	13. NDC Number *(if applicable)*	14. Serial Number *(if applicable)*
2 bottles	61958-2501-01	

15. Lot Number(s)
CDSFFA, 19BIC038A

16. Expiration Date(s)
Lot CDSFFA EXP: 12/2022 Lot 19BIC038A EXP: 3/2021

17. For Notification: Description of Event/Issue

On March 26, 2021 Safe Chain solutions sales representative received a complaint from a pharmacy customer that she had two patients complain that their prescribed bottle of BIKTARVY contained other medication. One patient identified the pills in the bottle to be another GILEAD medication, GENVOYA. Both patients returned the bottles to the pharmacy, and Safe Chain has instructed her to return the bottles to our facility to quarantine. Safe Chain has notified all trading partners of the complaint and has quarantined /any inventory of the affected lots. Notifications to customers were sent on 3/27/2021. We await further instruction regarding the disposition of these lots.

Add Page for Item 17

18. For Request for Termination of Notification: Description of why notification is no longer necessary

Add Page for Item 18

19. If you have submitted information to FDA through an alternative mechanism, check all that apply.

☐ BPDR ☐ MedWatch 3500 ☐ None
☐ FAR ☐ MedWatch 3500A ☐ Other *(Specify)*: _____

Company/Facility Information

20. Company Name & Address

Name	Safe Chain Solutions
Address 1 *(Street address, P.O. box, etc.)*	822 Chesapeake Drive
Address 2 *(Apartment, suite, unit, building, floor, etc.)*	
City	Cambridge
State/Province/Region	MD
Country	United States
ZIP or Postal Code	21613

21. Company Category *(Select from list)*

Wholesale Distributor

22. Unique Facility Identifier *(of company named in #20)*

025667294

23. Contact Information *(Note: For the telephone, you may enter the number of either the contact person or of the company named in #20.)*

Name	Charles Boyd
Telephone Number *(Include area code)*	855-437-5727 X1001
Email Address	charlesb@safechain.com

SUBMIT BY EMAIL

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Drug Notification

Form Approved: OMB No. 0910-0806
Expiration Date: January 31, 2022
See PRA Statement on page 2.

Refer to instruction sheet (Form FDA 3911 Supplement) for more information.

1. Type of Report *(Select one)*: ☐ Initial Notification ☒ Follow-Up Notification ☐ Request for Termination

2. Incident Number *(Provide this number, assigned by FDA, if you selected Follow-up Notification or Request for Termination above; see instructions.)* 45629496

3. Date of Initial Notification to FDA *(mm/dd/yyyy)*	4. Date Company Determined Product Was Illegitimate *(mm/dd/yyyy)*	5. Classification of Notification *(Select from list)*
03/27/2021		Unfit for Distribution

Description of Product

6. Name of Product as It Appears on Label
BIKTARVY 30CT

7. Primary Ingredients(s) *(if known)*
BICTEGRAVIR, EMTRICITABIN, TENOFOVIR ALAFENEMIDE FUMARATE

8. Drug Use *(Select from list)*	9. Drug Description *(Select from list)*
Human Use	Finished Prescription Drug

10. Strength of Drug	11. Dosage Form *(Select from list)*
50MG/200MG/25MG	Tablet

12. Quantity of Drug *(Number and Unit)*	13. NDC Number *(if applicable)*	14. Serial Number *(if applicable)*
2 bottles	61958-2501-01	

15. Lot Number(s)
CDSFFA, 19BIC038A

16. Expiration Date(s)
Lot CDSFFA EXP: 12/2022 Lot 19BIC038A EXP: 3/2021

17. For Notification: Description of Event/Issue

The customer who complained about these two lots was Columbia Heights Pharmacy located at 3316 14th St. NW, Washington DC 20010. Safe Chain compliance (Abbie Divilio) spoke with the PIC, Elizabeth Puwo who informed us that one bottle contained GENVOYA and was identified by the patient. The second bottle contained a green/blue tab and did not appear to be BIKTARVY. The patient informed the PIC that they called Gilead to ask about the pill color, and called the pharmacist. The pharmacist suggested she bring the bottle back to the pharmacy. Safe Chain has requested that the customer return the bottles, they have not arrived at the facility yet. Additional information can be provided once we receive the bottles in question.

Add Page for Item 17

18. For Request for Termination of Notification: Description of why notification is no longer necessary

Add Page for Item 18

19. If you have submitted information to FDA through an alternative mechanism, check all that apply.

☐ BPDR ☐ MedWatch 3500 ☐ None
☐ FAR ☐ MedWatch 3500A ☐ Other *(Specify)*: _____

Company/Facility Information

20. Company Name & Address

Name: Safe Chain Soltions

Address 1 *(Street address, P.O. box, etc.)*: 822 Chesapeake Drive

Address 2 *(Apartment, suite, unit, building, floor, etc.)*:

City: Cambridge | State/Province/Region: MD

Country: United States | ZIP or Postal Code: 21613

21. Company Category *(Select from list)*: Wholesale Distributor

22. Unique Facility Identifier *(of company named in #20)*: 025667294

23. Contact Information *(Note: For the telephone, you may enter the number of either the contact person or of the company named in #20.)*

Name: Charles Boyd | Telephone Number *(Include area code)*: 855-437-5727

Email Address: charlesb@safechain.com

SUBMIT BY EMAIL

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Drug Notification

Form Approved: OMB No. 0910-0806
Expiration Date: January 31, 2022
See PRA Statement on page 2.

Refer to instruction sheet (Form FDA 3911 Supplement) for more information.

1. Type of Report *(Select one)*: ☒ Initial Notification ☐ Follow-Up Notification ☐ Request for Termination

2. Incident Number *(Provide this number, assigned by FDA, if you selected Follow-up Notification or Request for Termination above; see instructions.)*

3. Date of Initial Notification to FDA *(mm/dd/yyyy)*	4. Date Company Determined Product Was Illegitimate *(mm/dd/yyyy)*	5. Classification of Notification *(Select from list)*
03/31/2021		Unfit for Distribution

Description of Product

6. Name of Product as It Appears on Label
Biktarvy 30CT

7. Primary Ingredients(s) *(if known)*
BICTEGRAVIR, EMTRICITABIN, TENOFOVIR ALAFENEMIDE FUMARATE

8. Drug Use *(Select from list)*	9. Drug Description *(Select from list)*
Human Use	Finished Prescription Drug

10. Strength of Drug	11. Dosage Form *(Select from list)*
50MG/200MG/25MG	Tablet

12. Quantity of Drug *(Number and Unit)*	13. NDC Number *(if applicable)*	14. Serial Number *(if applicable)*
1 bottle	61958-2501-01	

15. Lot Number(s)
6400501A

16. Expiration Date(s)

17. For Notification: Description of Event/Issue

Safe Chain Solutions compliance department and CEO, Charles Boyd were notified by the sales team representative that a customer had a complaint about one bottle of BIKTARVY. The customer, Global Express Pharmacy located at 10596 Garden Grove BLVD, Garden Grove, CA 92843, had a patient state that there was Stribild in their bottle of BIKTARVY. The patient recognized the pill as they had preciously been prescribed this medication. The PIC, Tuan, stated that he dispensed a closed bottle of BIKTARVY lot 6400501A to this patient. Safe Chain has asked the pharmacy to return the bottle to us, so that we may quarantine the product and await further instruction. Safe Chain has notified other customers who have purchased this lot.

Add Page for Item 17

18. For Request for Termination of Notification: Description of why notification is no longer necessary

Add Page for Item 18

19. If you have submitted information to FDA through an alternative mechanism, check all that apply.

☐ BPDR ☐ MedWatch 3500 ☐ None
☐ FAR ☐ MedWatch 3500A ☐ Other *(Specify)*: _____

FORM FDA 3911 (2/19 – PREVIOUS VERSION OBSOLETE) **Page 1 of 2** PSC Publishing Services (301) 443-6740 EF

Company/Facility Information

20. Company Name & Address

Name: Safe Chain Solutions

Address 1 *(Street address, P.O. box, etc.)*: 822 Chesapeake Drive

Address 2 *(Apartment, suite, unit, building, floor, etc.)*:

City: Cambridge | State/Province/Region: MD

Country: United States | ZIP or Postal Code: 21613

21. Company Category *(Select from list)*: Wholesale Distributor

22. Unique Facility Identifier *(of company named in #20)*: 025667294

23. Contact Information *(Note: For the telephone, you may enter the number of either the contact person or of the company named in #20.)*

Name: Charles Boyd | Telephone Number *(Include area code)*: 855-437-5727 X1001

Email Address: charlesboyd@safechain.com

SUBMIT BY EMAIL

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Drug Notification

Form Approved: OMB No. 0910-0806
Expiration Date: January 31, 2022
See PRA Statement on page 2.

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1. Type of Report *(Select one)*: ☒ Initial Notification ☐ Follow-Up Notification ☐ Request for Termination

2. Incident Number *(Provide this number, assigned by FDA, if you selected Follow-up Notification or Request for Termination above; see instructions.)*

3. Date of Initial Notification to FDA *(mm/dd/yyyy)*	4. Date Company Determined Product Was Illegitimate *(mm/dd/yyyy)*	5. Classification of Notification *(Select from list)*
04/07/2021	04/06/2021	Fraudulent Transaction

Description of Product

6. Name of Product as It Appears on Label
BIKTARVY, COMPLERA, GENVOYA, ODEFSEY, TRUVADA

7. Primary Ingredients(s) *(if known)*

8. Drug Use *(Select from list)*	9. Drug Description *(Select from list)*
Human Use	Finished Prescription Drug

10. Strength of Drug	11. Dosage Form *(Select from list)*
VARIES	Tablet

12. Quantity of Drug *(Number and Unit)*	13. NDC Number *(if applicable)*	14. Serial Number *(if applicable)*
177 bottles		

15. Lot Number(s)
multiple

16. Expiration Date(s)
multiple

17. For Notification: Description of Event/Issue

Safe Chain Solutions placed an order with our trading partner, Rapids Tex Wholesale (who uses MR Unlimited as a 3PL) located at 10333 Harwin Dr, Ste 263, Houston, TX for approximately 177 bottles of various HIV medications all manufactured by Gilead Sciences. Upon trying to verify the T3 information provided to us, Gilead informed Safe Chain that that T3 information was inconsistent with their records. They had no record of selling the products to Amerisource Bergen, and Amerisource Bergen let Gilead know that they did not sell these products to Rapids Tex. Upon Gilead's determination of the product, we quarantined the product.

Add Page for Item 17

18. For Request for Termination of Notification: Description of why notification is no longer necessary

Add Page for Item 18

19. If you have submitted information to FDA through an alternative mechanism, check all that apply.

☐ BPDR ☐ MedWatch 3500 ☐ None
☐ FAR ☐ MedWatch 3500A ☐ Other *(Specify)*: _____

Company/Facility Information

20. Company Name & Address

Name: Safe Chain Solutions

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22. Unique Facility Identifier *(of company named in #20)*: 025667294

23. Contact Information *(Note: For the telephone, you may enter the number of either the contact person or of the company named in #20.)*

Name: Charles Boyd | Telephone Number *(Include area code)*: 855/437/5727 X 1001

Email Address: charlesb@safechain.com

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